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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,288	04/01/2004	Michael Carl Junger	PA-5386-RFB	8573

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COOK GROUP PATENT OFFICE  
P.O. BOX 2269  
BLOOMINGTON, IN 47402

EXAMINER

BOUCHELLE, LAURA A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/816,288

Applicant(s)

JUNGER, MICHAEL CARL

Examiner

Laura A. Bouchelle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 3-5, 11, 13, 14, 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa et al (US 4634420) in view of Helfgott et al (US 4314560).
3. Spinosa discloses a separable flushing and aspiration needle; the flushing assembly comprising a needle 42 connectable to a source of flushing liquid 20; the aspiration assembly comprising a needle 14 connectable to an aspiration arrangement (See Abstract); and the aspiration needle extends coaxially within the flushing needle. See Fig. 1.
4. Spinosa discloses a handle 8, and outer needle 42 extending from the handle, a side port 98 connectable with a source of flushing liquid, an aspiration assembly comprising a proximal portion 56 connectable to an aspiration assembly, and a connection 58 arranged to join the aspiration assembly to the handle (Col. 10, lines 25-43). See Fig. 1.

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5. Spinosa discloses a first connector portion 47 on the handle and a second connector portion 58 on the aspiration cannula; and the aspiration cannula having a grip portion 56 that extends into the connector portion in use. See Fig. 1. Spinosa discloses that the connector portions are snap in locks (Col. 5, lines 35-38).

6. The tapered extension further comprises alignment detents 43, which engage with corresponding recesses on the connector portion. See Fig. 3. The connector portion further comprises an internally tapered wall. See Fig. 2.

7. Claims 3-5, 11, 13-15 differ from Spinosa in calling for the device to comprise an outer needle. Helfgott teaches an endophthalmic handpiece comprising an outer needle 18 that allows for insertion into the body. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Spinosa to include an outer needle as taught by Helfgott to allow for insertion of the device into the body.

8. Claims 6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa in view of Helfgott in view Emery et al (US 5160319). Claim 6 differs from Spinosa in view of Helfgott in calling for the outer needle to have a beveled tip. Emery teaches an oocyte retrieval needle comprising an outer needle with a beveled tip 68 allowing the physician to precisely puncture the follicle and release the oocyte (Col. 4, lines 55-68). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the outer needle of Spinosa in view of Helfgott to have a

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bevel as taught by Emery to allow the physician to precisely puncture the follicle and release the oocyte.

9. Claim 8 differs from the teachings above in calling for the distal end of the aspiration tip to terminate just within the beveled end of the outer needle. Claim 9 calls for the distal end to terminate between 0.5 and 1.5 mm proximally from the base of the beveled tip. Emery teaches an aspiration cannula 36 located within an outer cannula 30 wherein the aspiration cannula ends just proximal the beveled tip of the outer cannula so that rotation of the needle scrapes the follicle wall to dislodge the oocyte so that it can be aspirated (Col. 5, lines 34-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device of Spinoso in view of Helfgott so that the distal end of the aspiration tip to terminate just within the beveled end of the outer needle as taught by Emery so that rotation of the needle scrapes the follicle wall to dislodge the oocyte so that it can be aspirated.

10. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinoso in view of Helfgott in view of Emery et al as applied to claim 6 above, and further in view of West et al (US 6273877). Claim 7 differs in calling for the tip to further include a secondary bevel. West teaches a needle having a tip with a primary bevel and a secondary bevel that provide a sufficiently sharp distal end to penetrate the skin with little risk of excessive force urging the needle too far into the body (Col. 3, lines 15-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the outer needle of Spinoso in view of Helfgott in view of Emery to

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have a secondary bevel as taught by West to provide a sufficiently sharp distal end to penetrate the skin with little risk of excessive force urging the needle too far into the body.

11. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa et al in view of Helfgott in view of Davis et al (US 6018676). Claim 10 differs from Spinosa in calling for a portion at the distal end of the outer needle to be treated to improve its ultrasound echo characteristics. Davis teaches a needle comprising indenting, patterning or knurling to increase echogenicity of the needle (Col. 2, lines 35-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the outer needle of Spinosa in view of Helfgott to have indenting, patterning or knurling as taught by Davis to increase its echogenicity.

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinosa et al in view of Helfgott in view of Mottola et al (US 5533986). Claim 11 differs from Spinosa in calling for an O-ring on the connector portion. Mottola teaches the use of an O-ring to form a fluid tight seal between two separable parts of a catheter (Col. 9, lines 30-33). Furthermore, it is well known in the art to use an O-ring to ensure a fluid tight seal between two connectable parts. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the connector portion of Spinosa in view of Helfgott to include an O-ring as taught by Mottola to ensure a fluid tight seal between the two connecting portions.

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13. Claim 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spinoso in view of Helfgott in view of Knox (US 3561596). Claim 16 differs from Spinoso in calling for the assembly to be supplied in a sterile peel open package. Claim 17 differs in calling for the assembly to be provided in a disassembled state. Knox teaches a packaging for syringes, needles and the like wherein each element of a device can be supplied as a separate unit in an individual peel apart package that can be easily opened and kept sterile before use (Col. 4, lines 13-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Spinoso in view of Helfgott to be in a disassembled state in peel apart sterile packages as taught by Knox so that the package can be easily opened and kept sterile before use.

14. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Spinoso et al in view of Emery and further in view of and Davis. Claim 18 differs from Spinoso in calling for a beveled tip. Emery teaches an oocyte retrieval needle comprising an outer needle with a beveled tip 68 allowing the physician to precisely puncture the follicle and release the oocyte (Col. 4, lines 55-68). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the outer needle of Spinoso to have a bevel as taught by Emery to allow the physician to precisely puncture the follicle and release the oocyte.

15. Claim 18 further differs from the teachings above in calling for the needle to be treated to improve ultrasound echo characteristics. Davis teaches a needle comprising indenting, patterning or knurling to increase echogenicity of the needle (Col. 2, lines 35-

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39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the outer needle of Spinosa to have indenting, patterning or knurling as taught by Davis to increase its echogenicity.

*Response to Arguments*

16. Applicant's arguments filed 9/12/06 have been fully considered but they are not persuasive.

17. In response to applicant's argument that a physician would not consider the devices above when wishing to extract oocytes from an ovary, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

18. Applicant argues that Spinosa does not intend the components to be supplied separately to the physician. Spinosa is silent on the issue of whether or not the device is supplied in multiple components, and therefore, there is no reason to assume that the device cannot be supplied to the physician in two components.

19. Applicant argues that Helfgott does not disclose an outer needle. The outer tubular member of Helfgott appears to be a needle in that it is a long, thin, rigid, hollow member that punctures the skin. If applicant feels that outer needle of the current



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invention is distinct from the outer tubular member of Helfgott, it should be claimed in such a way as to distinguish it from the prior art.

*Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura A. Bouchelle whose telephone number is 571-272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Laura A Bouchelle  
Examiner  
Art Unit 3763

LAB

TECHNOLOGY CENTER 3763  
SUPERVISOR/EXAMINER  
TECHNOLOGY CENTER 3763